

REMARKS

After entry of this amendment, claims 1-24 will be pending. Claims 1-21 stand rejected. Claims 1, 4, 9, 10, 17 and 19 are amended. Claims 22-24 are added. Support for the amendments and new claims can be found, *inter alia*, in paragraphs [0022] and [0024] of the specification as filed and the figures. No new matter is added herein.

Applicants thank the Examiner for the courtesy extended during the in-person interview held April 23, 2007. Applicants confirm that the Interview Summary prepared by the Examiner is a complete and accurate record of the substance of the interview.

Applicants have thoroughly reviewed the Office action, including the Examiner's remarks and the references cited therein. Applicants submit that the following remarks are fully responsive to the Office action, and that all pending claims are patentable over the cited references.

Claim Objections

The Examiner objects to claim 10 for an informality. Claim 10 has been amended to correct the typographical error objected to by the Examiner.

Rejections Under 35 U.S.C. § 103

Claims 1-5, 9-11, 17, and 18

The Examiner rejects claims 1-5, 9-11, 17, and 18 under 35 U.S.C. § 103 as obvious over U.S. Patent No. 4,938,220 to Mueller Jr. ("Mueller") in view of U.S. Patent No. 6,562,049 to Norlander et al. ("Norlander") and U.S. Patent No. 5,830,222 to Makower ("Makower"). To establish a *prima facie* case of obviousness, the Examiner must demonstrate some suggestion or motivation to combine one or more references, with a reasonable expectation of success, to teach or suggest each and every claimed limitation. MPEP § 2142. Further, the Examiner must make explicit "an apparent reason to combine the known elements in the fashion claimed by the patent at issue[;]" mere conclusory statement are insufficient. KSR Int'l Co. v. Teleflex Inc., 500 U.S. ____

(2007). Applicants contend that the Examiner has failed to meet this burden with respect to the rejected claims. In particular, the asserted combination of references fails to teach or suggest the claimed invention.

Both claim 1 and claim 9 recite “a radiopaque marker located at a distal end of said sheath body, said radiopaque marker comprising a *radiopaque ring*[.]” (Emphasis added.) Claim 1 further recites that the “radiopaque marker may be split into two or more pieces along said at least one marker score line[.]” while claim 9 further recites that the “radiopaque marker may be split into two or more pieces along said at least one marker notch[.]” Similarly, claim 17 recites a “radiopaque marker comprising a *segmented radiopaque ring* including a first marker portion . . . wherein said first marker portion may be split apart from a remainder of said radiopaque marker along said gap[.]” (Emphasis added.)

The Examiner properly acknowledges that Mueller does not teach a score line, a notch, or a gap along which the radiopaque marker may be split into two or more pieces. Office action, para. 4. Rather, the Examiner relies upon Makower for this teaching. Applicants respectfully disagree with this reading of Makower. The scoring disclosed in Makower mars the surface of a metal in order to interfere with sound waves; there is no teaching or suggestion that the scoring permits the metal to be split into two or more pieces therealong. Makower, col. 4, lines 13-15. That is, the definition of “scoring,” as that term is used in Makower, is quite different from the definition of “score line” in the present invention. Thus, as the Examiner agreed during the April 23, 2007 interview, the teachings of Makower are inapposite to the claimed invention.

Norlander teaches coaxial splittable sheaths, either or both of which may be made radiopaque. Norlander, col. 10, line 63 to col. 11, line 4. However, as acknowledged by the Examiner during the interview and in the Interview Summary, a radiopaque splittable sheath is structurally distinguishable from a radiopaque ring as recited in the pending claims (“the difference between sheaths and rings – sheaths being more elongate and flexible”). To the extent that Norlander teaches a radiopaque metal band used in conjunction with the splittable sheaths, it does not disclose that the band is scored as recited in claim 1 or notched as recited in claim 9, much less that the

band can be split into pieces. To the contrary, Norlander teaches scoring *only* the sheath. Id., col. 6, lines 50-55.

Applicants accordingly respectfully contend that the asserted combination of references does not yield the claimed invention. In particular, Applicants submit that the asserted combination of references does not yield “a radiopaque marker . . . comprising a radiopaque ring . . . [that] may be split into two or more pieces” as recited in claims 1 and 9, or “a radiopaque marker . . . comprising a segmented radiopaque ring . . . [that] may be split apart from a remainder of said radiopaque marker” as recited in claim 17. Rather, the asserted combination of references yields one or more coaxial splittable sheaths (Norlander), which may themselves be radiopaque, and which incorporate a unitary, non-splittable radiopaque band (Mueller), which may also have a marred surface (Makower).

In light of the foregoing, Applicants respectfully contend that the Examiner has not established that independent claims 1, 9, and 17 are *prima facie* obvious. The dependent claims (2-5, 10, 11, and 18) are allowable for at least the same reasons as the independent claims from which they depend are allowable. The rejection of claims 1-5, 9-11, 17, and 18 is therefore improper and should be reconsidered and withdrawn.

Claims 6-8, 12-16, and 19-21

The Examiner rejects claims 6-8, 12-16, and 19-21 under 35 U.S.C. § 103 as obvious over Mueller, Norlander, and Makower, further in view of U.S. Patent No. 6,520,934 to Lee et al. (“Lee”). Applicants respectfully disagree.

The shortcomings of the combination of Mueller, Norlander, and Makower with respect to the independent claims are discussed at length above. The addition of Lee does not address or overcome these shortcomings. Therefore, claims 6-8, 12-16, and 19-21 are allowable for at least the same reasons as the independent claims from which they depend are allowable, and Applicants respectfully request reconsideration and withdrawal of the rejection thereof under section 103.

CONCLUSION

In view of the foregoing amendments and remarks, Applicants respectfully submit that the application is in condition for allowance, and request that all rejections be withdrawn, that all pending claims be allowed, and that the application be passed to issue. If, for any reason, the Examiner finds the application to be in other than condition for allowance, the Examiner is invited to contact the undersigned in an effort to resolve any matter still outstanding before issuing another action.

Applicants have provided for a two (2) month extension of time concurrently herewith. If any further extension of time is deemed necessary for this submission to be considered timely, Applicants hereby petition therefor.

Applicants believe that a fee of \$350 is due for the net addition of claims herein. Authorization is hereby granted to charge any fees, including fees for the net addition of claims and for any further extensions of time deemed necessary, to Deposit Account No. 50-1129 with reference to Attorney Docket No. 0B-044600US/82410-0054.

Respectfully submitted,

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